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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,621	10/19/2004	Petra Cirpus	12810-00043-US	6556
23416 7590 11/16/2009 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER				
MCILWAIN, ELIZABETH F				
ART UNIT		PAPER NUMBER		
1638				
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11/16/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/511,621

**Applicant(s)**

CIRPUS ET AL.

**Examiner**

Elizabeth F. McElwain

**Art Unit**

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 4-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed June 29, 2009 has been entered.

Claims 1, 12, 13, 15 and 16 are currently amended.

Claims 1 and 4-22 are pending and are examined on the merits.

### ***Specification***

The abstract is objected to for consisting of more than one paragraph.

Correction is required.

### ***Claim Objections***

- a. Claims 18 and 19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 on which they depend requires that the process uses nucleic acid sequences that are set forth in the claims.
- b. Claim 12 is objected to for reciting SEQ ID NO: 17 and 18, which are non-elected sequences.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 1 and 4-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knutzon et al (US 6,075,183 issued June 2000) taken with Beaudoin et al (PNAS Vol. 97, No. 12: 6421-6426) and Parker-Barnes et al (PNAS Vol. 97, No. 15: 8284-8289, July 19, 2000) and further in view of any one or more of: GenEMBL Accession AX214446 (Heinz et al, September 6, 2001), Girke et al (Plant J 15:39-48, 1998) and Mukerji (US Patent 7,067,285).
4. The claims are drawn to a method for producing compounds in a plant that comprise any of fatty acids from 9 carbons to 24 carbons and any of one double bond to five double bonds, wherein the sum of all of said fatty acids comprises at least 1% by weight of total fatty acid content, and the plant is produced by transforming the plant with a nucleic acid encoding a delta-6 desaturase, a delta-6 elongase, and a delta-5 desaturase from *Physcomitrella patens* and/or *Phaeodactylum tricornutum*, then growing and harvesting the plant.
5. Knutzon et al teach producing polyunsaturated fatty acids (PUFAs) by transforming plants, including the oilseed plant *Brassica* (canola, Example 7) with constructs comprising

nucleic acids encoding a delta-6 desaturase (Examples 2 and 8) or a delta-5 desaturase (Examples 1 and 7) in a construct operably linked to regulatory sequences for producing PUFAs including those with at least 20 carbon atoms and up to five carbon-carbon double bonds, and extracting the fatty acids from the plant seeds. Knutzon et al also teach that other delta-6 desaturase and a delta-5 desaturase coding sequences can be obtained from a variety of species using known methods (columns 5-6 and Example 3). In addition, Knutzon et al teach a delta-12 desaturase coding sequence (Example 4) and that two or more genes may be introduced into a host cell (column 10, lines 39-45). Knutzon et al also teach the enzymatic pathways for synthesis of PUFAs (Figures 1 and 2) using a delta-6 desaturase, a delta-6 elongase and a delta-5 desaturase, as well as other desaturases, such as a delta-12 desaturase, for example. Knutzon et al teach the desirability of producing PUFAs in plants in view of their value as dietary supplements and for pharmaceutical formulations, for example (see columns 1-2, for example).

6. Knutzon et al do not specifically teach a nucleic acid encoding a delta-6 elongase. Knutzon et al also do not specifically teach co-transformation with the coding sequences for all three of: a delta-6 elongase, a delta-6 desaturase and a delta-5 desaturase. Knutzon et al also do not teach said coding sequences from either *Physcomitrella patens* or *Phaeodactylum tricornutum*.

7. Beaudoin et al teach a nucleic acid encoding an elongase, which is shown to act as a delta-6 elongase by production of the expected products (see page 6423, the second column), and co-expression of this elongase with a delta-6 desaturase and a delta-5 desaturase coding sequence in yeast to produce PUFAs, such as arachidonic acid (see Table 3, for example). Beaudoin et al

also teach that an enzymatic pathway for production of PUFAs requires a delta-6 desaturase, a delta-6 elongase and a delta-5 desaturase (see Figure 1).

8. Parker-Barnes et al teach a nucleic acid encoding a delta-6 elongase, and co-expression of this delta-6 elongase with a delta-5 desaturase coding sequence in yeast to produce PUFAs, such as arachidonic acid. Parker-Barnes et al also teach that the enzymatic pathway for production of PUFAs that requires a delta-6 desaturase, a delta-6 elongase and a delta-5 desaturase.

9. GenEMBL Accession AX214446 is identical to SEQ ID NO: 3 encoding a delta-6 elongase from *Physcomitrella patens*.

10. Girke et al teach a delta-6 desaturase from *Physcomitrella patens* (see Figure 1, for example).

11. Mukerji teach a delta-6 desaturase from *Phaeodactylum tricornutum* (paragraph 194, Table 2, for example).

12. Given the recognition of those of ordinary skill in the art of the value of producing PUFAs in plants for the purpose of improving nutrition by transforming plants with nucleic acids encoding enzymes in the biosynthetic pathway, as taught by Knutzon et al, it would have been obvious to co-transform a plant with coding sequences for a delta-5 desaturase, a delta-6 desaturase and an elongase, given the teachings of Beaudoin et al and Parker-Barnes et al of co-transforming yeast with these three genes, and it would have been obvious to use any known coding sequences for any of these enzymes, including from species such as *Physcomitrella patens* and/or *Phaeodactylum tricornutum* that are known to comprise said coding sequences, as taught by any of GenEMBL Accession AX214446, Girke et al or Mukerji. In addition, the method used for liberating the fatty acids is a matter of choice, as is the choice of oilseed plant

species, and the particular amount of a given fatty acid would be the optimization of process parameters that would depend on the gene expression, the plant species, the developmental stage of the plant or seed and the growth conditions. Thus the claimed invention would have been prima facie obvious as a whole at the time the invention was made, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims are allowed.

It is noted that SEQ ID NO: 13 and SEQ ID NO: 21 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/  
Primary Examiner, Art Unit 1638